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| 28863 7590 02/22/2011 SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125 | | | | |
| EXAMINER KAHELIN, MICHAEL WILLIAM | | | | |
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/691,917
Filing Date: October 23, 2003
Appellant(s): SINGHAL ET AL.

Ambar P. Nayate
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/21/2010 appealing from the Office action mailed 12/28/2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

1, 5-19, 23-38, and 42-56

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5-19, 23-38, and 42-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner was unable to find support in the originally-filed application for the amended claim limitation of monitoring the therapy "while the output of the sensor was monitored." Although the portions of the disclosure cited by Applicant (e.g., par. 0035) appear to support defining

an event (e.g., running) and monitoring therapy delivered by the device during the event and/or during the "learning mode," the Examiner was unable to find support for monitoring therapy while defining the event (i.e., monitoring the sensor). For instance, the patient could begin the "event" (e.g., running) or initiate the learning mode; then the "event" is defined based on monitoring the sensor; and *subsequently* the therapy is monitored by the device (as shown in Applicant's Figures 5 and 6). These figures lack, and the corresponding text is also deficient in describing, an embodiment wherein the "initially defining" step occurs while "monitoring therapy" (i.e., performed in parallel). Just because these two acts are disclosed as occurring during the "learning mode," does not mean that one occurs "while" the other occurs because both could occur in the learning mode (or while the patient is running), but at different times. This appears to be an unsupported range of when the "monitoring therapy" and "monitoring the sensor" steps occur. Should these limitations be removed from the claims, the previous rejections of record will be applied.

(10) Response to Argument

**GROUND OF REJECTION TO BE REVIEWED ON APPEAL -- THE REJECTION OF
CLAIMS 1, 5-19, 23-38, AND 42-56 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

CLAIMS 1, 5-18, 49, 50, AND 55

The examiner's rejection is premised on the following elements: (i) the disputed new claim limitation requires simultaneous "monitoring of therapy" (e.g., monitoring the particular stimulation parameters applied to a patient) and "initially defining an event"

(e.g., recording a sensor output and defining that output to correspond to sitting, running, standing, etc.); (ii) the originally filed disclosure describes "monitoring a therapy" during a "learning mode"; (iii) the originally filed disclosure describes "initially defining an event" during a "learning mode"; (iv) the originally-filed disclosure lacks description of "monitoring a therapy" and "initially defining an event" at the same time during the "learning mode" (see, e.g., Figure 5's disclosure of these steps being performed in sequence/serially and not simultaneously).

Appellant argued that the claim limitation "monitoring therapy delivered by a medical device while the output of the sensor was monitored during the event to initially define the event" is supported by the original disclosure because of asserted implicit support provided in paragraphs [0062], [0035], [0059], and [0011]. Appellant argued that paragraph [0062] indicates that the sensor output can be recorded "over any length of time" or "at any time," and it allegedly therefore follows that "any time" includes simultaneously with the "monitoring of therapy." However, the examiner respectfully asserts that this "any length of time" language provides no more support for the more specific simultaneous monitoring than it would for a more specific length of time as "2.5 seconds" or "1 year" -- both of these examples clearly lacking written description support. In other words, this broad recitation of "any length of time" does not support any and all possible species that can be formulated within that range after prosecution has begun, so long as the species is not repugnant or contradictory to the genus. The examiner's position is that description of this specific combination (*i.e.*, "monitoring...while the output of the sensor was monitored") is lacking and the only

description of the relative temporal relationship between these two events lies in Figure 5, which shows the events occurring in sequence and not simultaneously. Furthermore, the disclosure that both occur during the "learning mode" is likewise not a description of simultaneous occurrence because the events could both occur during this mode in sequence (*e.g.*, as shown in Figure 5). As indicated in the Advisory Action of 3/12/2010, please consider the following analogy: disclosure of eating breakfast in the morning and getting dressed in the morning does not support the more specific case of eating breakfast while getting dressed. Likewise, Appellant's disclosure that both events occur during some "mode" or period of time does not support the concept that both "defining" and "monitoring" occur simultaneously.

In regards to Appellant's comments on the bottom of page 9 to page 10 of the Appeal Brief of 5/21/2010, the examiner has not and does not now dispute that the original disclosure supports monitoring therapy during an event (like running). The examiner does dispute that the original disclosure supports monitoring therapy while defining the event (like running), as the claims were amended to recite to avoid the prior art.

CLAIMS 19, 23-37, 51, AND 52

Similar comments apply to the similar claim limitations, as addressed above.

CLAIMS 38, 42-48, 53, AND 54

Similar comments apply to the similar claim limitations, as addressed above.

CLAIM 56

Similar comments apply to the similar claim limitations, as addressed above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Michael Kahelin/

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/Niketa I. Patel/

Supervisory Patent Examiner, Art Unit 3762

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TC 3700 TQAS